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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,624	04/09/2004	Michael John Dunkley	0197.00	8935
21968	7590	05/03/2005	EXAMINER	
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/821,624	Applicant(s) DUNKLEY ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-20 and 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13 and 21-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>DETAILED ACTION</u> |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: alignment guide of figures 1 and 2 or figure 4.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 20,27,28,29-34 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Tucker Guy on Monday April 18,2005 a provisional election was made without traverse to prosecute the invention of figures 1 and 2, claims 1-12,14-20,27-34.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 12, 21-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12,14-20,27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al.

US Patent 5,921,236 in view of Edwards WO/02/083220A2.

4. As to claim 1, Ohki et al. disclose an aerosolization apparatus (see fig.1 reference object 1) comprising: a housing (fig.2 inside the reference object 15) defining a chamber (fig.2 reference object 12) having one or more air inlets (fig.2 reference object 5), the chamber being sized to receive a capsule (see fig.4 reference object K) which contains an aerosolizable pharmaceutical formulation (in the form of powder, col.1 line 14); a puncturing mechanism (fig.2 reference object 27) within the housing, the puncturing mechanism comprising an alignment guide (fig.2 reference object 8) and a puncture member (fig.2 reference object 27A), wherein the alignment guide comprises a surface (fig.5 reference object 8A) adapted to contact (fig.5 seems to depict object 8A has a flat surface where a capsule contacts) the capsule while the puncture member is advanced into the capsule to create an opening (col.3 lines 14-15) in the capsule, and wherein at least a portion of the surface is sloped at an angle (fig.5 reference object 8

makes perpendicular angle to a base surface 8A), however do not disclose the angle is less than 55 degrees relative to the longitudinal axis of the capsule (as to the limitation "less than 55 degrees" applicant stated that the conventional alignment guides, such as those available from PH&T Pharm in Milan, Italy, and those described in PCT application WO 02/083220 have an angle of less than 33 degrees relative to the longitudinal axis, see specification page 8 lines 23-25. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the alignment guide of Ohki in view of the teachings of prior art in order to provide the guide with an angle less than 55 degrees for the purposes of properly aligning the capsule), and an end section (fig.2 reference object 20) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose (nasal cavities, col.1 lines 15-16) so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule.

5. As to claim 2, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle, which is from 35 to 55 degrees relative to the longitudinal axis of the capsule. As to claim 3, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle, which is from 37 to 50 degrees relative to the longitudinal axis of the capsule. As to claim 4, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle of about 45 degrees relative to the longitudinal axis of the capsule. As to claims 2-4, prior art as discussed above teaches an angle of less than 33 degrees relative to the longitudinal axis of the capsule. It is well known in the art that capsule comes in various sizes and shapes. Therefore, it is obvious to one of ordinary skills in the art to design the angle of the alignment member larger or smaller to respectively accommodate and align a larger or

smaller capsule size. Therefore, the angle limitations recited in claims 2-4 are not considered to be critical.

6. **As to claim 5, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the puncturing mechanism is at least partially within the chamber (fig.2 seems to depict a puncturing mechanism comprises a pin (27) situated within a chamber).

7. **As to claim 6, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein surface comprises a passageway (fig.2 reference object 8C) and wherein the puncture member slides (the puncture member slides when a force is delivered by reference object 15) within the passageway.

8. **As to claim 7, Ohki et al. do not disclose** an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the puncture member. **As to claim 8, Ohki et al. do not disclose** an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the chamber. **As to claim 9, Ohki et al. do not disclose** an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to an inhalation direction. **As to the underlined limitations of claims 7-9, Ohki's figure 2 seems to depict an inhalation device at its longitudinal axis where the inhalation direction is toward a nose piece (20), also depicts the puncture member, chamber, and surface are aligned at/parallel to the longitudinal axis of the inhalation device. Since the surface makes an angle less than 55 degrees relative to the longitudinal axis, it would have been obvious to one of ordinary skills in the art to inherently achieve a same angle relative to any elements (i.e. puncture member, chamber, inhalation direction) aligned along the longitudinal axis of the inhalation device.**

9. **As to claim 10, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the surface is moveable (col.2 lines 29-31) within the chamber.

10. **As to claim 11, Ohki et al. do not disclose** an aerosolization apparatus according to claim 10 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the direction of movement of the surface, **however as discuss cussed above, figure 2 depicts an inhalation device at its longitudinal axis, and the surface makes an angle relative to that axis. Since the surface is movable as disclosed by Ohki et al., it would have been obvious to one of ordinary skills in the art to recognize that the angle is also movable relative to the direction of the movement of the surface as well.**

11. **As to claim 13, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the surface comprises one or more protrusions (see fig.5 reference object 8D) and wherein the one or more protrusions are adapted to (fig.5 seems to depict a capsule is situated between the two protrusion members) contact the capsule.

12. **As to claim 14, Ohki et al. do not disclose** an aerosolization apparatus according to claim 1 wherein the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber. **However, Ohki's figures depict that a capsule is positioned within a chamber inside an inhaler. By comparing figure 1 to any of the other figures it would have been obvious to one of ordinary skills in that art that end section of figure 1 has to be removed in order to provide an access to the chamber for the purposes of positioning a capsule inside the chamber.**

13. **As to claim 15, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the puncture mechanism comprises a pair of puncture members (fig.5 reference objects 27 and 28).

14. **As to claim 16, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the puncture member is adapted to (each puncture member is designed to puncture one hole at one end of the capsule, see col.2 lines 45-58) puncture only one end of the capsule.

15. **As to claim 17, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the chamber is elongated (fig.2 reference object 12 is considered elongated) and wherein the capsule is received lengthwise (fig.5 seems to depict a capsule is situated in lengthwise direction in a chamber) within the elongated chamber.

16. **As to claim 18, Ohki et al. disclose** Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the width of the chamber is less than the length of the capsule (fig.2 seems to depict a capsule is situated in a chamber where the chamber has a width less than the length of the capsule).

17. **As to claim 18, Ohki et al. disclose** n aerosolization apparatus according to claim 1 wherein the inlet is shaped to create a swirling (the airflow causes the powder to be aerosolized, therefore the flow is considered swirling air-flow) airflow within the chamber.

18. **As to claim 19, Ohki et al. disclose** an aerosolization apparatus comprising: a housing (fig.2 inside the reference object 15) defining a chamber (fig.2 reference object 12) having one or more air inlets (fig.2 reference object 5), the chamber being sized to receive a capsule (fig.5 reference object K) which contains an aerosolizable pharmaceutical formulation (in the form of powder, col.1 line 14); a puncturing mechanism (fig.2 reference object 27) within the housing, the puncturing mechanism comprising an alignment guide (fig.2 reference object 8) and a puncture member (fig.2 reference object 27), wherein the alignment guide comprises a surface (fig.2 reference object) adapted to contact (fig.5 seems to depict object 8A has a flat surface where a capsule contacts) the capsule while the puncture member is advanced into the capsule to create an opening (col.3 lines 14-15) in the capsule, and wherein the surface comprises

one or more protrusions (fig.5 reference object 8D) for contacting the capsule; and an end section (fig.2 reference object 20) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose (Ohki discloses a nasal inhaler, see col.1 lines 6-8) so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule.

19. **As to claim 20, Ohki et al. disclose** an aerosolization apparatus according to claim 20 wherein surface comprises a passageway (fig.2 reference object 8C) and wherein the puncture member slides (the puncture member slides when a force is delivered by reference object 15) within the passageway.

20. **As to claim 21, Ohki et al. disclose** an aerosolization apparatus according to claim 20 wherein the inlet is shaped to create a swirling (inlet has long narrow opening, upon actuation air forcing out of the narrow opening into a larger chamber will create swirling of air-flow, and the term "spray" used throughout Ohki's disclosure is considered an equivalent of swirling air-flow, see also col.2 lines 55-65) airflow within the chamber.

Conclusion

21. The prior art made of record on form PTO-892 and not relied upon discloses aerosolized inhalation device.

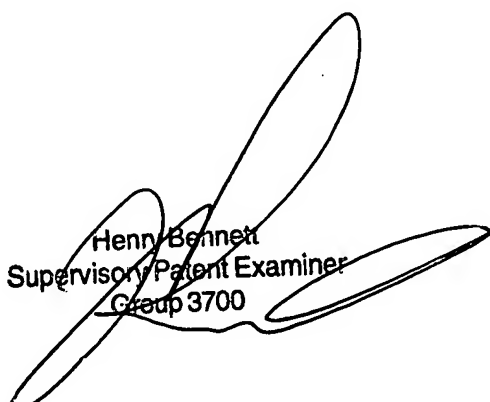
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4: 30 pm.

23. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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